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Deadly Germ Behind Infant Formula Shortage Joins CDC Watchlist of Bad Bugs + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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Deadly Germ Behind Infant Formula Shortage Joins CDC Watchlist of Bad Bugs

Associated Press reported:

> U.S. health officials will start formally tracking infections caused by the rare but potentially deadly germ that sickened babies and triggered a nationwide shortage of infant formula last year.
>
> A group that advises the Centers for Disease Control and Prevention agreed Thursday to add infections caused by cronobacter to the list of serious conditions reported to the agency. There are about 120 infections and diseases on the national watchlist.
>
> States will be asked, but not required, to notify the CDC about cronobacter infections, although they usually comply. Such infections are required to be

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reported now in only two states, Minnesota and Michigan. The change will take effect next year, though states may begin reporting earlier.

An outbreak of cronobacter infections that started in 2021 sickened four infants fed formula from Abbott Nutrition's Sturgis, Michigan, plant. Two of the babies died. No direct link was found between the Abbott products and the infections, but FDA officials shuttered the plant after contamination and other problems were detected. Abbott recalled top brands of infant formula, triggering a massive nationwide shortage that lasted for months.

EU Secures Vaccine Deals With Pfizer and Others for Future Pandemic

Reuters reported:

> The European Commission has secured deals with Pfizer (PFE.N) and several European drugmakers to reserve capacity to make up to 325 million vaccines per year in case of a future global health emergency, it said on Friday.
>
> The agreement, first reported by Reuters, covers mRNA, vector-based and protein-based vaccines and does not relate to existing COVID-19 vaccine agreements between the EU and vaccine makers including U.S.-based Pfizer.
>
> The European Commission said Europe needs to be better prepared for future health emergencies. The deal ensures that companies are ready to respond to a crisis by keeping their facilities up to date and monitoring their supply chains, "including stockpiling where necessary", the Commission said in a statement.
>
> The Commission has selected Pfizer's plants in Ireland and Belgium to reserve the capacity to produce mRNA vaccines. It selected Spanish companies Reig Jofre (RJFE.MC) and Laboratorios Hipra SA to reserve capacity for protein-based vaccines and Bilthoven Biologicals B.V. of the Netherlands for vector-based vaccines.

Moderna Billionaire Set to Score 3,000% Gain on Tiny Biotech

Bloomberg reported:

> Noubar Afeyan became a billionaire backing Moderna Inc., the dark horse biotech firm that became a household name due to its lifesaving COVID vaccine. He just added to his fortune after another one of his long-shot bets quintupled in value.
>
> Sigilon Therapeutics Inc. soared 438% to $21.15 Thursday after Eli Lilly agreed to buy the biotech. Funds of Afeyan's venture capital firm, Flagship Pioneering, own 31.9% of Sigilon, according to the company's latest proxy filing.
>
> Afeyan could potentially receive an even larger payout if Sigilon hits certain benchmarks. If all the criteria are met, it would boost Lilly's offer as high as $126.56 per share and bump his firm's windfall to $101 million.
>
> Like Moderna, Sigilon is based in Cambridge, Massachusetts. It also shares a co-founder: MIT professor Robert Langer, who also became a billionaire through the vaccine maker.

Sanofi Outlines Five-Pronged Approach to Reel in €10B in Vaccine Sales by 2030

Fierce Pharma reported:

> While Dupixent often steals the show, Sanofi isn't sleeping on its vaccine franchise. Boasting prophylactic prospects in respiratory syncytial virus (RSV), pneumococcal disease and flu — including a clutch of promising mRNA candidates — the French pharma feels confident its shots can

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deliver billions of dollars by the end of the decade.

By 2030, Sanofi figures its immunizations could generate more than €10 billion in annual sales, the company said during a vaccines R&D event Thursday. Much of that momentum hinges on Sanofi's pipeline, where the company is targeting an "accelerated pace of innovation" in a bid to launch at least five innovative phase 3 vaccine programs by 2025.

All told, Sanofi's vaccine portfolio brought home €7,229 billion (about $7.9 billion) in sales for all of 2022. Between 2018 and 2022, Sanofi grew vaccine revenues by 8%, with two of the company's shots — Fluzone High Dose and the pediatric vaccine Penta/Hexaxim — achieving blockbuster status.

As for the company's lofty sales target, Sanofi is leveraging a five-pronged plan. First, it aims to become a leader in RSV thanks to its AstraZeneca-partnered antibody blockbuster-in-waiting Beyfortus, plus a pair of experimental shots.

Xylazine Present in More Than 1 in 10 Fentanyl Overdose Deaths in the U.S.

CNN Health reported:

The Biden administration recently declared fentanyl laced with xylazine — an animal sedative commonly known as "tranq" — to be an emerging threat facing the United States, and a new analysis of toxicology reports illustrates its sharp rise.

In June 2022, xylazine was present in nearly 11% of fentanyl overdose deaths, almost a four-fold increase from January 2019, when the combination was present in about 3% of cases, according to the report.

The data, published Thursday by the U.S. Centers for Disease Control and Prevention, is from a subset of states that participated in the CDC's State Unintentional Drug Overdose Reporting System. The researchers note that reporting practices have varied over time and by jurisdiction and increased prevalence could partially reflect greater awareness and testing. However, even more, consistent testing for xylazine is necessary to grasp the true scale of the issue going forward, they wrote.

Fentanyl, which has been driving the opioid crisis in recent years, is a fast-acting opioid. One hypothesis as to why xylazine may be added is that it may extend the duration of the high the drug provides, but experts also said it may just be used as a bulking agent to boost a seller's supply.

We Have a Cure for Hepatitis C — so Why Aren't More People Getting Treatment?

STAT News reported:

Over the past decade, scientists have developed new therapeutic drugs to combat hepatitis C. Simple, orally administered direct-acting antiviral (DAAs) drugs, such as the combination medicine sofosbuvir/velpatasvir, can cure the highly contagious disease effectively within just 12 weeks.

But these breakthrough treatments are not getting to the people who need them, according to a Centers for Disease Control and Prevention study released Thursday. Only one in 3 adults diagnosed with the disease has been cured since 2013 when those highly effective curative drugs for hepatitis C were first approved in the U.S.

The medications cost roughly $24,000 per course of treatment, posing a major barrier to many people infected with hepatitis C. These accessibility issues are "really disappointing," said Francis Collins, former director of the National Institutes of Health, who is now leading a proposed program for the federally funded national elimination of hepatitis C plan in the U.S. "I don't think we as a society can look at that and say that's OK — it's not OK."

Stanford Study of Paxlovid for Long COVID Stopped Early — Enrollment Was Halted Earlier Than Planned After Interim Analysis

MedPage Today reported:

> Enrollment into a small trial of nirmatrelvir/ritonavir (Paxlovid) for long COVID — one that previously garnered attention for investigators not wearing masks — has been stopped early after an interim analysis, Stanford University confirmed to MedPage Today.
>
> Two sources familiar with the STOP-PASC study told MedPage Today that trial enrollment had been halted. One was told by a study coordinator that a preliminary review found "inconclusive evidence" for the primary outcome of the study. Another said their first appointment was canceled just a few days before it was supposed to take place, and they were later told that all future enrollment had been halted.
>
> According to ClinicalTrials.gov, the study design specified two-way masking, for both investigators and participants. Neither Stanford nor study sponsor Pfizer would comment on whether or not the masking issue factored into the decision to stop the study early.
>
> Stanford spokesperson Kim said the results of the STOP-PASC trial "will be shared as soon as the study is completed," and that the study should be published "sometime before the end of the year" but that there is no definite timeline.

China's CSPC Pharma Partners With Pfizer for Oral COVID Treatment

Reuters reported:

> Chinese drug maker CSPC Pharmaceutical Group (1093.HK) said on Thursday it signed a strategic partnership with Pfizer (PFE.N) to launch a local brand of an oral COVID-19 treatment, in an attempt to improve access to treatment in China.
>
> The combination of Nirmatrelvir and Ritonavir sold under the brand name Paxlovid, an oral small molecule developed by pharmaceutical company Pfizer, is used to treat patients suffering from mild to moderate COVID-19 symptoms and who are at risk of disease progression. In December 2021, the U.S. Food and Drug Administration authorized the use of Paxlovid, making it the first drug for COVID-19 that can be taken at home.
>
> China, whose home-grown vaccines are seen as less effective than the Moderna (MRNA.O) and Pfizer (PFE.N)-BioNTech (22UAy.DE) mRNA shots, has been racing to develop vaccines using messenger RNA (mRNA) technology since early 2020.
>
> Earlier this year, CSPC said China had approved its first domestically developed mRNA vaccine against COVID-19, a major achievement in a country that has declined to use Western COVID shots to support domestic research.

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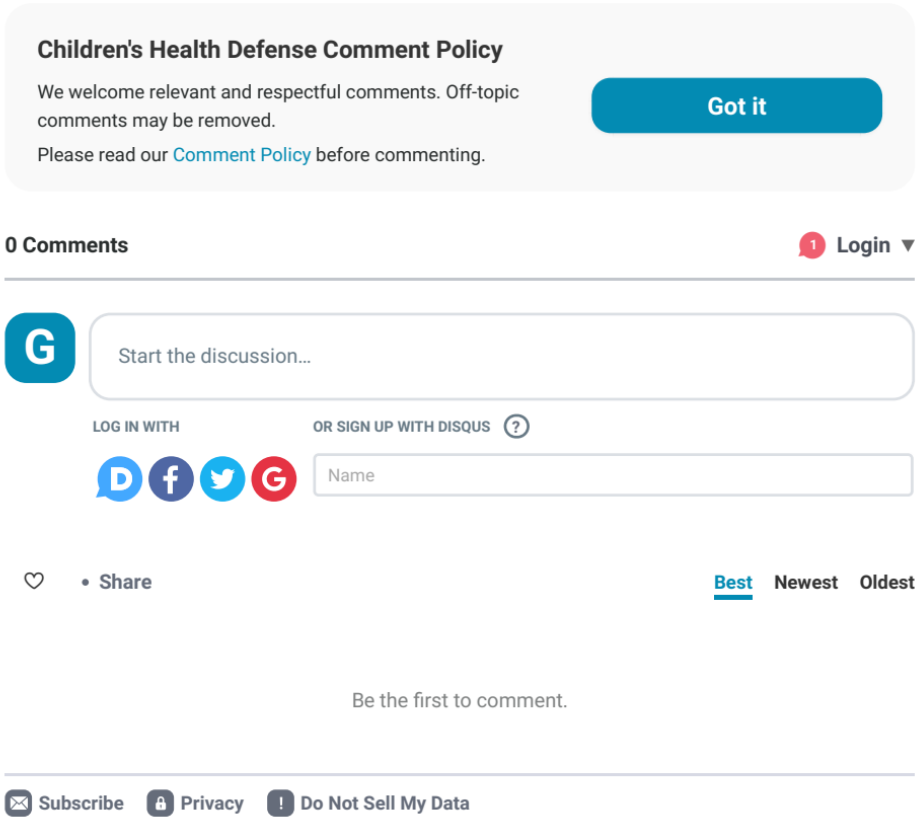

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